(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 February 2004 (19.02.2004)

PCT

(10) International Publication Number
WO 2004/014270 A1

(51) International Patent Classification[7]: A61F 11/00, A61B 17/56

(21) International Application Number: PCT/AU2003/001012

(22) International Filing Date: 11 August 2003 (11.08.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2002950754 9 August 2002 (09.08.2002) AU

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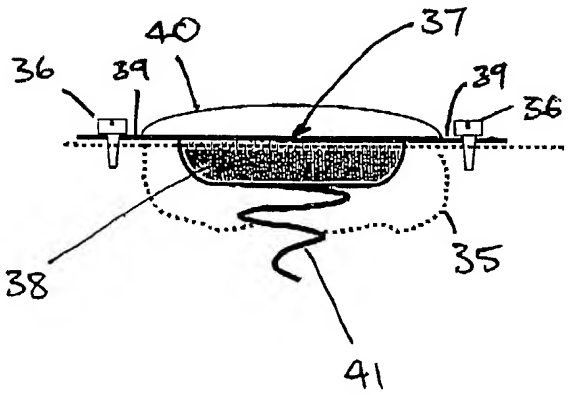
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: MECHANICAL DESIGN FOR A COCHLEAR IMPLANT



(57) Abstract: A protective faceplate (37) for an implantable component of a tissue-stimulating prosthesis, such as a cochlear implant. The faceplate (37) comprising a first or outer surface and an opposed second or inner surface. The implantable component can be removably or non-removably mountable to the second surface and adapted to extend into a cavity formed in a bone of a recipient.

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"Mechanical design for a cochlear implant"

Field of the Invention

The present invention resides in an improved mechanical design for the implantable component of an implantable medical device, such as a cochlear implant.

Background of the Invention

In many people who are profoundly deaf, the reason for deafness is absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into nerve impulses. These people are unable to derive suitable benefit from conventional hearing aid systems, no matter how loud the acoustic stimulus is made, because there is damage to or absence of the mechanism for nerve impulses to be generated from sound in the normal manner.

It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve.

Cochlear implant systems have typically consisted of essentially two components, an external component commonly referred to as a processor unit and an internal implanted component commonly referred to as a receiver/stimulator unit. Traditionally, both of these components have cooperated together to provide the sound sensation to a user.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that converts the detected sounds, particularly speech, into a coded signal, a power source such as a battery, and an external transmitter antenna coil.

The coded signal output by the speech processor is transmitted transcutaneously to the implanted receiver/stimulator unit situated within a recess of the temporal bone of the user. This transcutaneous transmission occurs via the external transmitter

antenna which is positioned to communicate with an implanted receiver antenna coil provided with the receiver/stimulator unit.

This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted receiver/stimulator unit. Conventionally, this link has been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

The implanted receiver/stimulator unit traditionally includes a receiver antenna coil that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal to an intracochlear electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

As mentioned above, traditional implanted receiver/stimulator units are positioned within the head of the recipient by drilling a bed into and through the posterior section of the mastoid bone lying behind the recipient's ear. Such a bed is usually made by drilling the bone down to the lining of the brain or dura mater, so that the receiver/stimulator unit is securely held in position and does not protrude excessively past the skull surface.

The receiver/stimulator unit manufactured by the present Applicant has a package made from titanium which houses the stimulation electronics and which is fitted into a bed created in the mastoid bone. A receiver antenna coil extends from the rear end of the package and lies superficial to the bone. Other cochlear implants have included packages made from a ceramic material which are usually placed completely within the bed drilled down to the lining of the brain.

Over time it has been realised that the placing of the above packages in the mastoid bone some distance behind the ear has not always been ideal and has had some problems associated therewith. In instances where young children have been implanted with a device, it has been seen that in some recipients the package has created an external protuberance in the region of the head adjacent the implant site, which has been unsightly, intrusive, and inconvenient for the recipient. In some instances, such a

protuberance can prevent the placement of a behind-the-ear processor unit over the site of the implant due to the risk of skin erosion that may result.

Further, as the package is positioned to be facing the surface of the skull, the implant package may be subject to an impact to the head in that region either directly on top of the device or as a lateral glancing blow to the device. In this regard, such devices must be designed to withstand such an impact and remain operational. In this regard, it has been found that by designing the device to have a low profile, the risk of the device sustaining a glancing, lateral blow is less likely. It is also important that the device is designed in such a manner to ensure that it is prevented from entering the cranial cavity in the event of the device being subject to an impact of excessive force.

International PCT Application No. PCT/AU00/00936 discloses an implant package capable of being located within the mastoid cavity of a recipient. This application introduces the utilisation of the naturally occurring gutter lying between the sigmoid sinus, posterior osseous ear canal, the mastoid tip and the floor of the middle fossa to protect and maintain the implant package in place. This application discloses a suitably shaped implant casing capable of fitting wholly within the mastoid cavity, having a receiver coil connected thereto via flexible arms. Such a package design may have problems associated with stability of the implant within this cavity region, which could be greatly dependant upon the anatomy of the patient and the particular surgical approach used by the surgeon. Should the package be not firmly secured within the cavity, the implant may move following implantation causing tissue erosion and/or movement of the attached electrode arrays, possibly resulting in the need for re-implantation of the device.

Therefore, there is a need to provide a cochlear implant package that is capable of addressing at least some of the concerns with prior art devices.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

The present invention provides an arrangement that preferably allows an implantable package of a medical device to be securely positioned in a region of the recipient's head in a manner that preferably ensures that the contents of the implant package are protected from damage caused by a direct impact.

Further, the invention preferably provides an implant package that can quickly and simply be securely fixed in place without necessarily having to drill a conventional bed into the mastoid bone to house the implant and use sutures and the like to fix the package in place. Such conventional fixation means are time consuming and complicated, as particularly in the case of small children, there is a risk of drilling the bed through the dura mater. For example, by using the cavity formed by the mastoidectomy to house the implant package there is no need to drill a specific bed and channel in the bone to hold the implant package and lead in place, and this reduces the overall surgery time and minimises trauma to the patient. It is, however, to be appreciated that the present invention can be used in a situation where it is necessary to form a cavity by, for example, drilling a cavity into the bone.

According to a first aspect, the present invention is a medical implant for implantation in a cavity of a bone of a recipient, the implant comprising a hermetically sealed housing positionable within the bone cavity and having an upper surface and a lower surface, the upper surface having at least one flange member extending outwardly in at least one direction for a distance beyond the outward extent of at least a porion of the lower surface of the housing, said at least one flange being adapted to abut the surface of the bone surrounding the cavity.

The cavity can be formed in the bone ready for implantation of the implant or can be a natural cavity in the bone of the recipient. It will be appreciated that a natural cavity may be increased in size or changed in shape to suit the requirements of the implant.

In this aspect, the upper surface can have a configuration such that it is in substantial alignment with all of the surface of the bone immediately surrounding the cavity.

In a further embodiment, the lower surface of the housing can be configured to at least substantially match the shape and/or dimensions of the bone cavity.

In this aspect, the at least one flange member can extend outwardly in the at least one direction for a distance beyond the outward extent of all of the lower surface of the housing. The at least one flange is preferably adapted to be securable to the bone surrounding the cavity.

In a preferred embodiment, the upper surface can have two outwardly extending flanges, said flanges extending in opposite directions relative to each other.

One, more, or all of the flanges can be conformable to the surface of the bone of the recipient surrounding the cavity. The flanges can be adjusted in their orientation and/or shape preferably by finger pressure. In this regard, the flanges can be formed from a material that allows the flanges to be conformed to the surface of the bone. In another embodiment, the flanges can have a construction such that they are conformable to the bone surface. In this regard, the flanges may have a thickness that allows the flanges to be suitably conformable during the surgical implantation procedure. In a still further embodiment, both the properties of the material and the construction of the flanges may play a role in ensuring the flanges are conformable. The flanges are preferably conformable by finger pressure exertable on the flanges by a surgeon during the surgical implant of the implantable component.

In a still further embodiment, the upper surface of the housing can be formed of a conformable material so as to at least substantially match the surface of the bone surrounding the cavity. The upper surface of the housing can be formed from a malleable material, and preferably a biocompatible malleable metal. In one embodiment, the upper surface of the housing can be formed from a malleable titanium.

In yet another embodiment, the at least one flange can be an integral extension of the upper surface of the housing.

In another embodiment, the at least one flange can be formed separately and so be mountable to the upper surface.

In these embodiments, the at least one flange can have at least one orifice extending therethrough. This orifice can be adapted to receive a bone fixation device, such as a bone screw, a bone clip, and/or a bone nail.

In a still further embodiment, the upper surface and lower surface can be integrally joined to form the housing. In another embodiment, the upper surface and lower surface can be formed separately and then joined together. The join between the upper and lower surfaces is preferably such so as to ensure there is a hermetic seal between the surfaces. In these embodiments, the lower surface can be formed of a conformable material so as to at least substantially match the shape of the bone cavity. In this regard, the lower surface can be formed of a malleable material, preferably a biocompatible metal, such as a malleable titanium. The malleable material preferably allows the shape of the lower surface of the housing to be adjusted to suit the shape of the cavity that is to receive the housing.

In this aspect, the medical implant is preferably an implantable component of a tissue-stimulating prosthesis. Still further, the tissue-stimulating prosthesis is preferably a cochlear implant with the implantable component comprising a receiver/stimulator unit of such an implant.

According to a second aspect, the present invention is a protective faceplate for an implantable component of a tissue-stimulating prosthesis, the faceplate comprising a first surface and an opposed second surface, the implantable component being mountable to the second surface and adapted to extend into a cavity formed in a bone of a recipient.

In a first embodiment of this aspect, the faceplate is preferably adapted to be implantable in the bone of the recipient such that the first surface is aligned with or relatively closely adjacent the surface of the bone receiving the implant.

In a preferred embodiment of this aspect, the faceplate has a flange that extends outwardly in at least one direction for a distance greater than the outward perimeter of

the implantable component mountable thereto. In one embodiment, the faceplate can have two flanges extending outwardly in opposite directions relative to each other. In a still further embodiment, the faceplate can have two or more flanges extending outwardly from one end of the faceplate and two or more flanges extending outwardly from another end of the faceplate. Said another end can be distal said one end.

Each of the flanges are preferably adapted to abut the surface of the bone into which the implantable component extends following positioning of the component in the bone. In one embodiment, the flanges are preferably conformable to the surface of the bone. In this regard, the flanges can be formed from a material that allows the flanges to be conformed to the surface of the bone. In another embodiment, the flanges can be constructed so as to be conformable to the bone surface. In this regard, the flanges may have a thickness that allows the flanges to be suitably conformable during the surgical procedure. In a still further embodiment, both the properties of the material and the construction of the flanges may play a role in ensuring the flanges are conformable. The flanges are preferably conformable by finger pressure exertable on the flanges by a surgeon during the surgical implant of the implantable component.

In one embodiment, the flanges can have a thickness between about 0.05mm and 0.4mm, more preferably between about 0.1mm and 0.2mm. In this and other embodiments, the faceplate can have a thickness between about 0.3mm and 1mm. In one embodiment, the flanges can constitute an integral extension of the faceplate. In another embodiment, the flanges can be formed separately and be mountable to the faceplate.

In one embodiment, the faceplate and/or flanges can be formed of titanium. In this and other embodiments, the implantable component can comprise a housing also formed from titanium. In another embodiment, the housing of the implantable component and/or the faceplate can be formed of other materials, including suitable biocompatible ceramic and polymeric materials. In this regard, the faceplate and housing do not need to be formed of the same material. For example, the faceplate could be formed of a polymeric material, such as polypropylene or polytetrafluoroethylene, while the housing is formed of a ceramic or metallic material.

In a still further embodiment, the flanges are preferably securable to the surface of the bone. In one embodiment, one or more of the flanges can have orifices passing

therethrough. These orifices can be adapted to receive bone fixation devices, such as bone screws, bone clips and/or bone nails. In one embodiment, the bone screws can be countersunk, or have a round head. Still further, the bone fixation devices can be resorbable.

In one embodiment, the faceplate is preferably adapted to be secured to the bone at the site of each flange thereof. It will, however, be appreciated that there may be instances where it is not possible to use a particular flange due to a previous cavity having been formed in the bone, or the presence of a skull growth line, or a region of bone weakness.

In a further embodiment, the faceplate can be integrally formed with the housing of the implantable component of the tissue-stimulating prosthesis. In another embodiment, the faceplate can be separately formed from the housing of the implantable component and then mounted thereto in essentially a non-removable manner. Techniques such as welding and brazing can be envisaged as techniques for mounting the faceplate to the implantable component.

In a still further embodiment, the housing of the implantable component can be removably mounted to the faceplate. In this embodiment, the faceplate or housing of the implantable component can be provided with engagement means adapted to engage with the housing or faceplate, respectively. In one embodiment, the second surface of the faceplate can have one or more clips adapted to engage with the housing of the implantable component. In this embodiment, it is envisaged that the housing of the implantable component may not be mounted to a faceplate until surgery is underway and the size and shape of the faceplate required for that particular surgery has been determined.

In the above embodiments, the faceplate, flanges and/or bone fixation devices can be coated with a layer of silicone rubber or other suitable elastomeric material. The bone fixation devices would preferably be accessible by means of a slit or hole formed or formable in the material of the coating layer.

In a preferred embodiment, the tissue-stimulating prosthesis is a cochlear implant, with the implantable component comprising the receiver/stimulator package of such an implant. In this regard, the cavity preferably comprises a cavity formed in the

mastoid of the recipient during the implantation procedure. In this embodiment, the faceplate and/or the flanges extending therefrom can be dimensioned and/or shaped such that the faceplate is stabilised on the rim of the mastoidectomy.

An electrically conducting lead preferably extends from the receiver/stimulator package to an electrode array. The lead preferably exits the package such that it is extendable into the mastoid cavity on appropriate positioning of the implantable component and faceplate within the recipient. In a preferred embodiment, the lead preferably extends from the implanted package to the cochlea via a posterior tympanotomy positioned at the bottom of the mastoid cavity. Other lead positions and geometries are can, however, be envisaged.

According to a third aspect, the present invention is a method of implanting a medical implant in a cavity in a bone of a recipient, the implant having a housing having an upper surface and at least a conformable lower surface, the method comprising the steps of:

(i) forming or selecting a cavity in a bone of the recipient;

(ii) determining the shape of the cavity;

(iii) conforming the lower surface to at least substantially match the shape of the cavity in the bone;

(iv) positioning the implant in the cavity such that the upper surface is at least in substantial alignment with at least a portion of the surface of the bone surrounding the cavity.

In this aspect, the lower surface of the housing can be formed of a malleable material. Still further, the implant can have one or more features of the implant defined according to the first aspect of the present invention.

According to a fourth aspect, the present invention is a method of implanting an implantable component of a tissue-stimulating prosthesis in the bone of a recipient, the method comprising the steps of:

(i) forming or selecting a cavity in a bone of the recipient;

(ii) determining the shape of the cavity;

(iii) selecting a faceplate as defined herein and having a suitable shape and/or dimensions such that on placement, the first surface of the faceplate is aligned with or adjacent the surface of the bone surrounding the cavity; and

(iv) positioning the faceplate with the implantable component mounted thereto over the cavity.

According to a fifth aspect, the present invention is a method of implanting an implantable component of a cochlear implant in a mastoid cavity of a recipient, the method comprising the steps of:

(i) performing a mastoidectomy to form a cavity in the mastoid of the recipient;

(ii) determining the dimensions of the mastoid cavity;

(iii) selecting a faceplate as defined herein and having a suitable shape and/or dimensions such that on placement, the first surface of the faceplate is aligned with or adjacent the surface of the bone surrounding the mastoid cavity; and

(iv) positioning the faceplate with the implantable component mounted thereto over the mastoid cavity.

In a preferred embodiment of the fourth and fifth aspects, the faceplate can be mounted to the bone around the cavity therein. In this regard, suitable bone fixation devices as defined herein can be used to secure the faceplate to the bone.

In the fourth aspect, the method preferably comprises, prior to the positioning of the faceplate, the steps of performing a posterior tympanotomy and cochleostomy and then inserting an electrode array with a conducting lead extending back therefrom into the cochlea.

As defined, the present invention provides in part a faceplate that is suitable for use in appropriately mounting a receiver/stimulator package of a cochlear implant in a mastoid cavity formed in a recipient. In addition to supporting the package, the faceplate has the additional characteristic of serving to protect the package from impacts that might otherwise dislodge or destroy the receiver/stimulator package if positioned using conventional techniques.

Brief Description of the Drawings

By way of example only, a preferred embodiment of the invention is now described with reference to the accompanying drawings, in which:

Fig. 1 is a pictorial representation of a conventional cochlear implant system;

Fig. 2 is a representation of a conventional receiver/stimulator unit positioned in a bed fashioned in the mastoid bone according to conventional surgical techniques;

Fig. 3 is a simplified view of the receiver/stimulator unit and faceplate of a cochlear implant device according to a preferred embodiment of the present invention;

Fig. 4a is an end view of the unit and faceplate of Fig. 3 depicted implanted in the mastoid of a recipient;

Fig. 4b is a side view of the unit and faceplate arrangement of Fig. 3;

Fig. 5 is a simplified view of another embodiment of a faceplate and receiver/stimulator unit according to the present invention; and

Fig. 6 is an end view of yet another embodiment of a receiver/stimulator unit and faceplate of a cochlear implant device according to the present invention.

Preferred Mode of Carrying out the Invention

Before describing the features of the present invention, it is appropriate to briefly describe the construction of one type of known cochlear implant system with reference to Fig. 1.

Known cochlear implants typically consist of two main components, an external component including a speech processor 29, and an internal component including an implanted receiver and stimulator package 22. The external component includes a microphone 27. The speech processor 29 is, in this illustration, constructed and arranged so that it can fit behind the outer ear 11 and is held in place behind the outer ear 11 via an ear-hook arrangement (not shown). Alternative versions may be worn on the body. Attached to the speech processor 29 via a cable 13 is a transmitter antenna coil 24 that transmits electrical signals to the implanted package 22 via a radio frequency (RF) link.

The implanted component includes a receiver antenna coil 23 for receiving power and data from the transmitter coil 24. A cable 21 extends from the implanted receiver and stimulator package 22 to the cochlea 12 and terminates in an electrode array 20. The signals thus received are applied by the array 20 to the basilar membrane 8 and the nerve cells within the cochlea 12 thereby stimulating the auditory nerve 9. The operation of such a device is described, for example, in US Patent No. 4532930, the contents of which is incorporated herein by reference.

Fig. 2 shows in more detail the surgical placement of the implanted receiver and stimulator package 22 of Fig. 1, according to conventional practices. The package 22 is in the form of a capsule, for example a titanium capsule, which houses the necessary circuitry required for the implant to operate as desired. The receiver coil 23 is shown encapsulated in a material, such as silicone rubber, to provide a protective body and ensure fatigue resilience. A magnet 30 is shown positioned within the coil to assist in the alignment of the transmitter antenna coil 24 with the receiver antenna coil 23 as discussed previously. As is shown, a bed is drilled into the bone 31 to maintain the package 22 in position. This bed is typically round or ovoid to match the shape of the package. The bed is typically made in the mastoid bone and mastoid angle of the parietal bone in the region of the asterion. Typically, the bed is fashioned initially with a cutting burr, and then completed with a diamond paste burr and a template is typically used to ensure that the bed is fashioned to the correct size. As is shown, the bed may be drilled down to the lining of the brain, or dura mater 32, particularly for young children with thin skulls. It is for this reason that a diamond paste burr may be used when approaching the dura and when the dura is exposed, to minimise the risk of tearing of the dura 32.

As can be seen from Fig. 2, once the receiver and stimulator package 22 is secured in place in the mastoid bone, it remains rather unprotected, with only a layer of skin (not depicted) covering the skull protecting the package from any direct impact. Further to this, it can be appreciated that any impact in the direction shown by the arrow A of Fig. 2, has the potential for the package to tear the dura 32 and enter the cranial cavity, potentially causing damage to the sensitive structures of the brain. As can also be appreciated from Fig. 2, an impact to the head region of the recipient, particularly in the direction shown by arrow B, has the potential to dislodge the implant from its bed within the skull bone. Such dislodgement can cause damage to the area of the head adjacent the device as well as discomfort to the recipient. Any dislodgment of

the device also has the potential to require further surgical procedures to relocate the device in the desired position within the head of the recipient.

The present invention aims to address the above potential problems by positioning the receiver/stimulator package in the head in a manner whereby the package preferably has a low profile and its contents are afforded some protection from impact and from being subsequently damaged and/or dislodged.

During a typical surgical procedure for implanting a conventional cochlear implant device, such as this shown in Figs. 1 and 2, a mastoidectomy and posterior tympanotomy are typically employed to obtain access to the middle ear. The mastoidectomy procedure typically requires removal of material from the mastoid bone behind the ear of the patient via a cutting burr or drill. Typically, the cortex of the mastoid superior and posterior to the external meatus is removed and the excavation is deepened and air cells are removed superior and posterior to the meatus, exposing the mastoid antrum and the middle ear via the tympanotomy. Following the tympanotomy, the round window should be accessible, thereby allowing a cochleostomy to be performed and the electrode array inserted.

It can be understood that by performing a mastoidectomy, a cavity is created which could thereby house the receiver/stimulator package at a location remote from the exterior wall of the skull. It is considered that by allowing the mastoid cavity to house the implant package, considerable advantages can be obtained in relation to the protection and safety of positioning the implant package and the other advantages as discussed previously.

As discussed previously and disclosed in International PCT Patent Application PCT/AU00/00936, anatomical dissections have shown that there exists a "gutter" lying between the sigmoid sinus, posterior osseous ear canal, the mastoid tip and the floor of the middle fossa. This gutter can also form an ideal location to place the implantable receiver/stimulator package, in a positioned not exposed above the surface of the bone and protected by the pinna.

Fig. 3 is a view of one preferred embodiment of the present invention. In this embodiment, the mastoid cavity is shown by the fine dotted line 35, which is shown as being located behind the pinna 11. An upper surface in the form of a top faceplate 37

of the implanted receiver/stimulator unit 38 (heavy dotted line) is shown positioned above and over the mastoid cavity 35. As is evident in Fig. 3, the receiver/stimulator unit 38 has a lower surface that is shaped to be sunk into the mastoid cavity. The depicted faceplate 37 has flanges 39 which extend outside the perimeter of the implanted receiver/stimulator unit 38 to enable securing of the unit to the skull via surgical screws 36. A receiver antenna coil 40 is shown external of the unit 38 and faceplate 37, in much the same manner as a conventional design as discussed previously.

Figs. 4a and 4b show end and side views of the embodiment depicted in Fig. 3 and where appropriate, the same reference numerals are used. As can be clearly seen in these figures, the receiver/stimulator unit 38 extends into the mastoid cavity 35 and is protected by the faceplate 37 which acts as a protecting shield for the unit 38 as well as a stabiliser and means for securing the unit 38 in place. A lead 41 connects the receiver/stimulator unit 38 to the intracochlear electrodes (not shown) which deliver the electrical stimulation to the nerves within the cochlea.

The flanges of the faceplate 37 can be a simple extension of the upper surface of the receiver/stimulator unit and made from the same material as the rest of the receiver/stimulator unit. This material can, for example, be titanium, preferably a malleable titanium. Alternatively, a titanium flange may be attached to the titanium case of the receiver/stimulator unit 38 by an appropriate welding or other method.

The flanges 39 are formed so as to be relatively robust whilst also sufficiently malleable so that the entire faceplate 37 can be formed to the shape of the skull surrounding the mastoid cavity by the surgeon using finger pressure only. As the anatomy of this region of the head varies somewhat from individual to individual, it is desirable to form the flanges 39 so that they adopt a flush fit in abutment against the skull.

As the faceplate 37 provides protection for the receiver/stimulator unit 38, it is advantageous to form the faceplate from one of a number of different thicknesses of titanium sheet. In order to withstand impacts of considerable force it is desirable to form the faceplate 37 out of a suitable material such as titanium having a thickness of between 0.3 to 1 mm. As the flanges 39 must be malleable to enable a surgeon to alter their shape with a minimum of force, the flanges 39 are, in the depicted embodiment,

made from a thinner material than that of the faceplate 37. Alternatively, the desired conformability of the flanges 39 could be achieved by altering their geometry rather than their thickness. In this regard, the flanges 39 could be of the same thickness as the faceplate 37, provided that the flanges are in a narrower strip form rather than a wide flange form. However, in a preferred embodiment, the flanges 39 may be formed from a material, such as titanium, having a thickness of, for example, 0.1 to 0.2 mm.

The lead 41 is preferably pre-coiled so that it can settle into the mastoid cavity 35, below the receiver/stimulator unit 38. As is shown in Figs. 4a and 4b, the lead 41 exits the receiver/stimulator unit 38 from a bottom surface thereof. This facilitates routing of the lead to the cochlea via the posterior tympanotomy, which is at the bottom of the mastoid cavity. However, it is envisaged that the lead exit point and the form can have many other geometries and still remain within the spirit of the invention. For example, the lead 41 may exit from the side of the receiver/stimulator unit and may be straight.

In order to prevent tissue erosion, the faceplate 37, flanges 39 and screws 36 are preferably coated in a silicone rubber or other elastomeric material. In such a case, the screws 36 would be accessed by means of a slit or hole in the silicone above the screw 36.

It should be appreciated that the screws 36 used in the present invention may have a number of design variations to satisfy the design requirements of the present application. For example, the screws 36 may be countersunk for low profile, may have a round head, and may even be resorbable screws. Resorbable screws would assist in holding the implant in place for a short period until the fibrous tissue surrounds and secures the device in place.

Fig. 5 depicts an alternative embodiment of the present invention. In this embodiment, the faceplate has relatively narrow flanges 39 that are adapted to assist in enabling the faceplate 37 to conform to the contours of the skull. Further to this, extra screw holes are provided to allow some redundancy in the variations in patient anatomy and the mastoidectomy performed. Also, if there is a problem with securing the device at one screw site, such as a cavity from a past surgery or a skull growth line, then that screw may be omitted and an alternative screw site used. It should be stressed that this aspect of the present invention is important particularly as it is recommended against

fixing the device with screws on both sides of the natural growth lines of the skull. In this embodiment, the basic size of the faceplate 37 is designed to be just larger than the size of the mastoid cavity 35, allowing the faceplate 37 to be stabilised on the rim of the mastoidectomy. To assist in this stabilisation, the rim of the mastoid cavity may be easily flattened by the surgeon, for example by drilling, to create a stable seat for the faceplate 37.

Fig. 6 depicts yet another embodiment of the present invention. In this embodiment, the faceplate and flanges are not fixedly attached to the receiver/stimulator unit 38. The primary difference between this embodiment and that described in Figs. 4a and 4b is that the faceplate 37 is provided with mechanical catches or clips 45 to hold and maintain the receiver/stimulator unit 38 in place. In this manner, the receiver/stimulator unit is 'snap-fit' into the faceplate 37 for securing in place.

The benefit of this embodiment is that the use of the faceplate and flanges to secure the implant in place is optional and can be decided upon at the time of surgery. Further, the securing mechanism can be used with non-metallic receiver/stimulator units as there is no need for the faceplate and flanges to be welded onto the unit casing. This enables the present device and method to be employed with ceramic cased implants. It is also envisaged that with a detachable system as shown in Fig. 6, the faceplate/flange combination could be made from a non-metallic material such as a biocompatible plastic, as welding to the implant case would not be required. Such a feature would avoid the need to coat the surface of the faceplate and flanges with a coating of silicone rubber and the like to prevent tissue erosion. For example, the plate could be made of polypropylene or polytetrafluoroethylene (PTFE) which have the properties suitable for such an application.

In each of the above-described embodiments of the present invention, the receiver/stimulator unit 38 is shown as an arbitrarily shaped unit capable of fitting within the bone cavity. It is considered that the receiver/stimulator unit 38 could also be conformable such that the shape of the unit 38 may be altered during the procedure to conform to the specific shape of the bone cavity. In this regard, the unit 38 can be made of a conformable material that allows the shape and form of the unit to be changed without effecting the hermiticity of the unit 38.

In each of the above-described embodiments, the procedure associated with implanting a device according to the present invention could generally be as follows:

1. A mastoidectomy would be performed in the same manner as a conventional procedure;
2. Device placement would be determined using a template shaped like the actual implant device;
3. Drill holes would be marked for securing the device in place following the insertion of the electrode array;
4. A posterior tympanotomy and cochleostomy would be performed in the same manner as a conventional procedure;
5. The electrode array would be inserted into the cochlea;
6. The implant package would be placed in position. In this step, the coil connecting the package to the electrode array inserted into the cochlea would preferably coil itself up into the mastoid cavity due to the preformed coil in the lead; and
7. The implant package would be secured in place via screws or the like.

In this manner, the process for implanting a device of the present invention would in no way complicate a conventional procedure and would eliminate the need to drill an additional bed in the mastoid bone for receiving the implant.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS:

1. A medical implant for implantation in a cavity of a bone of a recipient, the implant comprising a hermetically sealed housing positionable within the bone cavity and having an upper surface and a lower surface, the upper surface having at least one flange member extending outwardly in at least one direction for a distance beyond the outward extent of at least a portion of the lower surface of the housing, said at least one flange member being adapted to abut the surface of the bone surrounding the cavity.

2. The medical implant of claim 1 wherein the lower surface is configured to at least substantially match the shape and dimensions of the bone cavity.

3. The medical implant of claim 1 wherein the upper surface has a configuration such that it is in substantial alignment with all of the surface of the bone surrounding the cavity.

4. The medical implant of claim 1 wherein the flange member extends outwardly in said at least one direction for a distance beyond the outward extent of all of the lower surface of the housing.

5. The medical implant of claim 4 wherein said at least one flange is securable to the surface of the bone surrounding the cavity.

6. The medical implant of claim 5 wherein the upper surface has two outwardly extending flanges, said flanges extending in opposite directions relative to each other.

7. The medical implant of claim 5 wherein said at least one flange is conformable to the surface of the bone of the recipient.

8. The medical implant of claim 1 or claim 7 wherein the upper surface of the housing is formed of a conformable material so as to at least substantially match the surface of the bone surrounding the cavity.

9. The medical implant of claim 8 wherein at least the upper surface of the housing is formed from a malleable material.

10. The medical implant of claim 9 wherein the malleable material is a biocompatible metal.

11. The medical implant of claim 1 wherein said at least one flange is an integral extension of the upper surface of the housing.

12. The medical implant of claim 1 wherein said at least one flange is formed separately and is mountable to the upper surface.

13. The medical implant of claim 4 wherein said at least one flange has at least one orifice extending therethrough, said orifice being adapted to receive a bone fixation device.

14. The medical implant of claim 13 wherein said bone fixation device is a bone screw, a bone clip, and/or a bone nail.

15. The medical implant of claim 1 wherein said upper surface and said lower surface are integrally joined to form the housing.

16. The medical implant of claim 1 wherein said upper surface and said lower surface are formed separately and joined together with an hermetic seal.

17. The medical implant of claim 15 or claim 16 wherein said lower surface is formed of a conformable material so as to at least substantially match the shape of the bone cavity.

18. The medical implant of claim 17 wherein said lower surface is formed of a malleable material.

19. The medical implant of claim 18 wherein said lower surface is formed of a biocompatible metal.

20. The medical implant of claim 1 wherein the medical implant is an implantable component of a tissue-stimulating prosthesis.

21. The medical implant of claim 20 wherein the tissue-stimulating prosthesis is a cochlear implant and the implantable component comprises a receiver/stimulator unit of such an implant.

22. A protective faceplate for an implantable component of a tissue-stimulating prosthesis, the faceplate comprising a first surface and an opposed second surface, the implantable component being mountable to the second surface and adapted to extend into a cavity formed in a bone of a recipient.

23. The protective faceplate of claim 22 wherein the faceplate has at least one flange that extends outwardly in at least one direction for a distance greater than the outward perimeter of the implantable component mountable thereto.

24. The protective faceplate of claim 23 wherein the faceplate has two flanges extending outwardly in opposite directions relative to each other.

25. The protective faceplate of claim 23 wherein said at least one flange is conformable to the surface of the bone of the recipient surrounding the cavity.

26. The protective faceplate of claim 23 wherein said at least one flange constitutes an integral extension of the faceplate.

27. The protective faceplate of claim 23 wherein said at least one flange is formed separately and is mountable to the faceplate.

28. The protective faceplate of claim 23 wherein said at least one flange is securable to the surface of the bone.

29. The protective faceplate of claim 28 wherein said at least one flange has at least one orifice passing therethrough, said orifice being adapted to receive a bone fixation device.

30. The protective faceplate of claim 29 wherein said bone fixation device is a bone screw, a bone clip and/or a bone nail.

31. The protective faceplate of claim 23 wherein said implantable component has a housing and said faceplate is integrally formed with said housing.

32. The protective faceplate of claim 23 wherein said implantable component has a housing and said faceplate is separately formed from the housing of the implantable component and then mounted thereto.

33. The protective faceplate of claim 32 wherein the housing of the implantable component is removably mounted to the faceplate.

34. The protective faceplate of claim 33 wherein the faceplate or housing of the implantable component is provided with engagement means adapted to engage with the housing or faceplate, respectively.

35. The protective faceplate of claim 33 wherein the second surface of the faceplate has one or more clips adapted to engage with the housing of the implantable component.

36. The protective faceplate of claim 22 wherein the tissue-stimulating prosthesis is a cochlear implant, with the implantable component comprising a receiver/stimulator unit of such an implant.

37. A method of implanting a medical implant in a cavity in a bone of a recipient, the implant having a housing having an upper surface and at least a conformable lower surface, the method comprising the steps of:

(i) forming or selecting a cavity in a bone of the recipient;

(ii) determining the shape of the cavity;

(iii) conforming the lower surface to at least substantially match the shape of the cavity in the bone;

(iv) positioning the implant in the cavity such that the upper surface is at least in substantial alignment with at least a portion of the surface of the bone surrounding the cavity.

38. The method of claim 37 wherein at least the lower surface of the housing is formed of a malleable material.

39. The method of claim 37 wherein the upper surface of the housing is formed of a conformable material.

40. The method of claim 39 wherein the upper surface of the housing is formed of a malleable material.

41. A method of implanting an implantable component of a tissue-stimulating prosthesis in the bone of a recipient, the method comprising the steps of:

(i) forming or selecting a cavity in a bone of the recipient;

(ii) determining the shape of the cavity;

(iii) selecting a faceplate as defined in claim 22 and having a suitable shape and/or dimensions such that on placement, the first surface of the faceplate is aligned with or adjacent the surface of the bone surrounding the cavity; and

(iv) positioning the faceplate with the implantable component mounted thereto over the cavity.

42. A method of implanting an implantable component of a cochlear implant in a mastoid cavity of a recipient, the method comprising the steps of:

(i) performing a mastoidectomy to form a cavity in the mastoid of the recipient;

(ii) determining the dimensions of the mastoid cavity;

(iii) selecting a faceplate as defined in claim 22 and having a suitable shape and/or dimensions such that on placement, the first surface of the faceplate is aligned with or adjacent the surface of the bone surrounding the mastoid cavity; and

(iv) positioning the faceplate with the implantable component mounted thereto over the mastoid cavity.

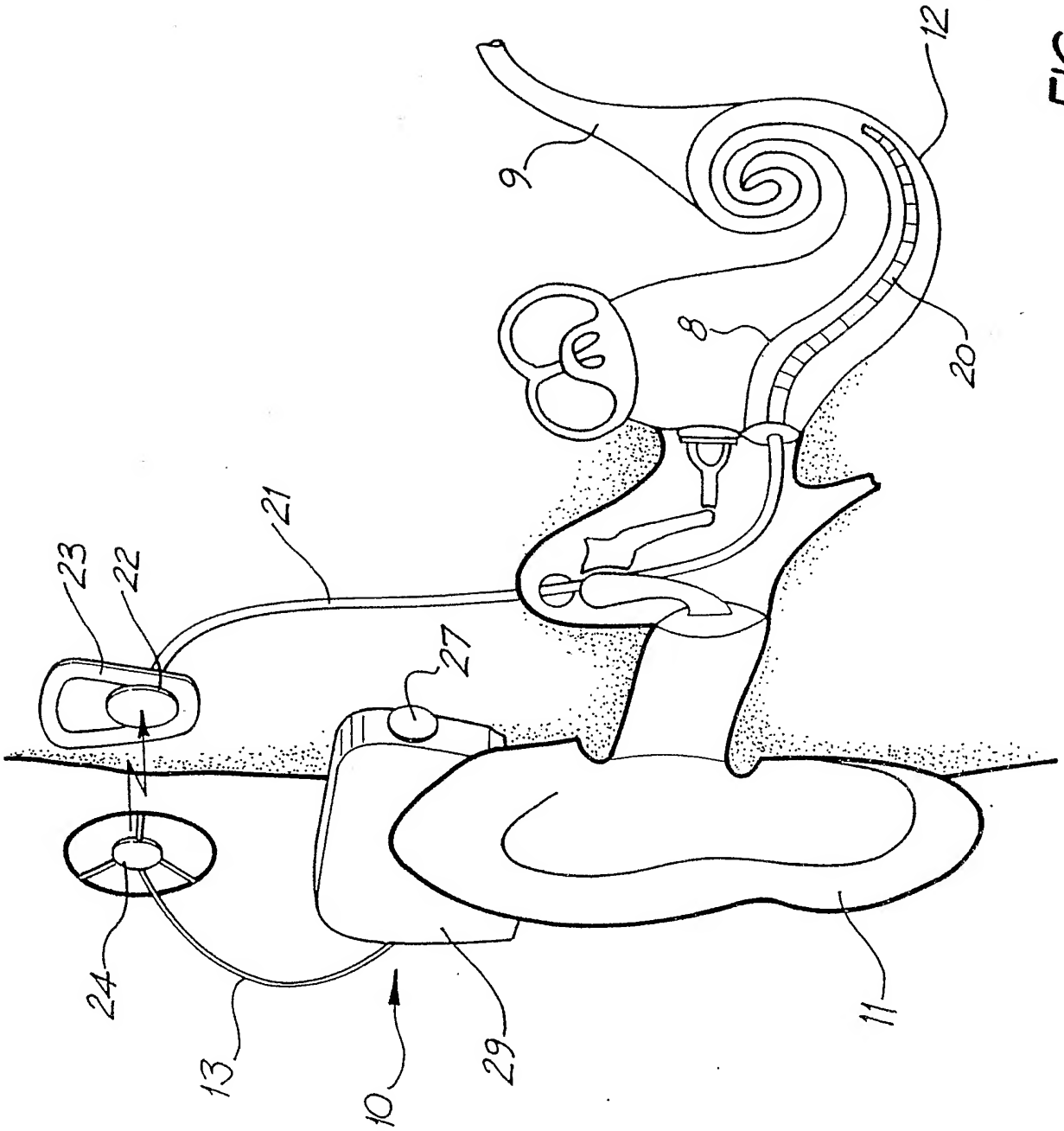

FIG. 1

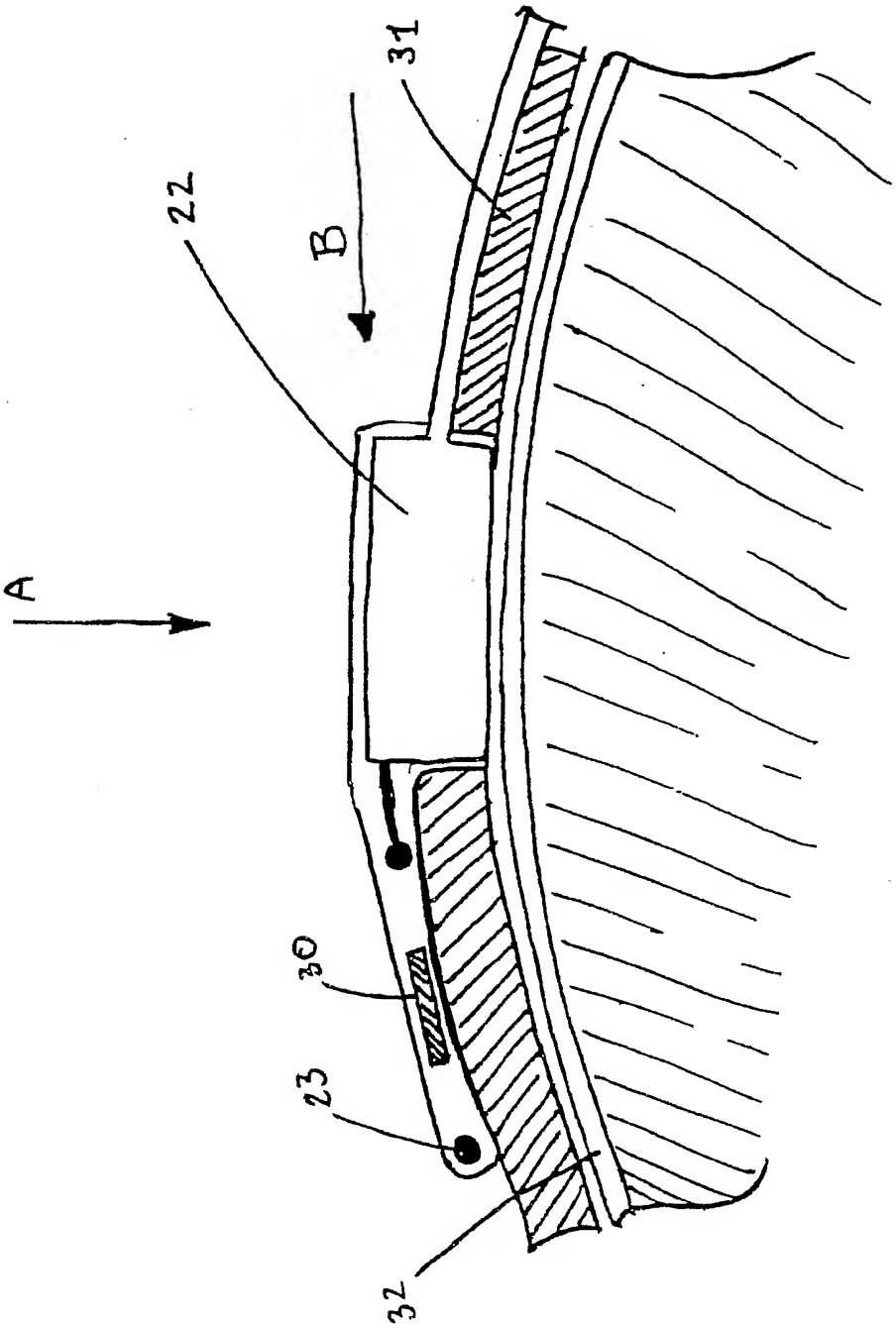

Figure 2

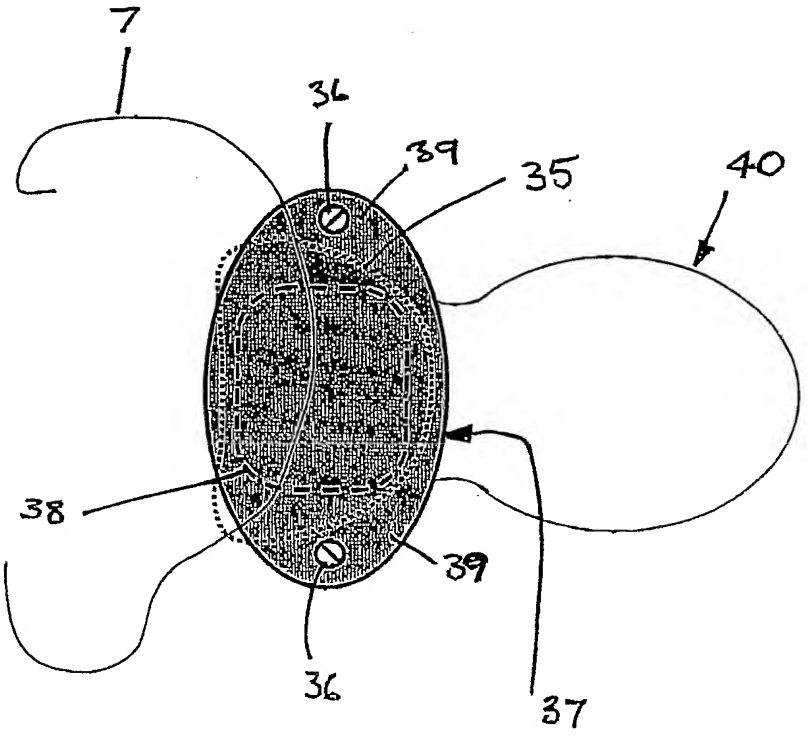

Figure 3

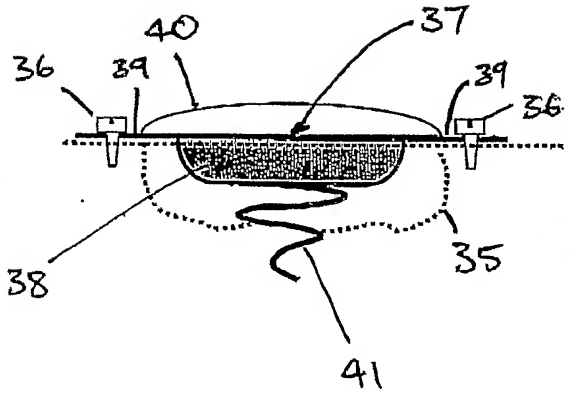

Figure 4a

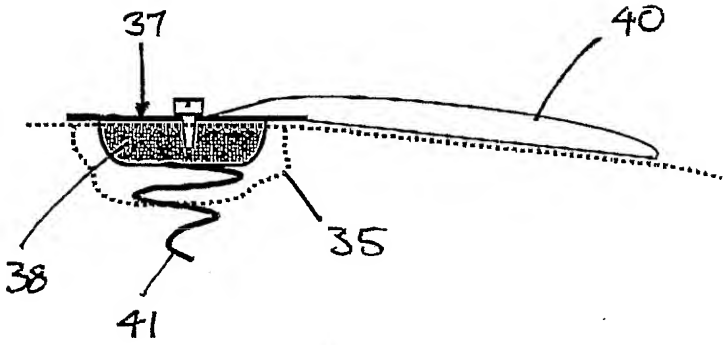

Figure 4b.

Figure 4

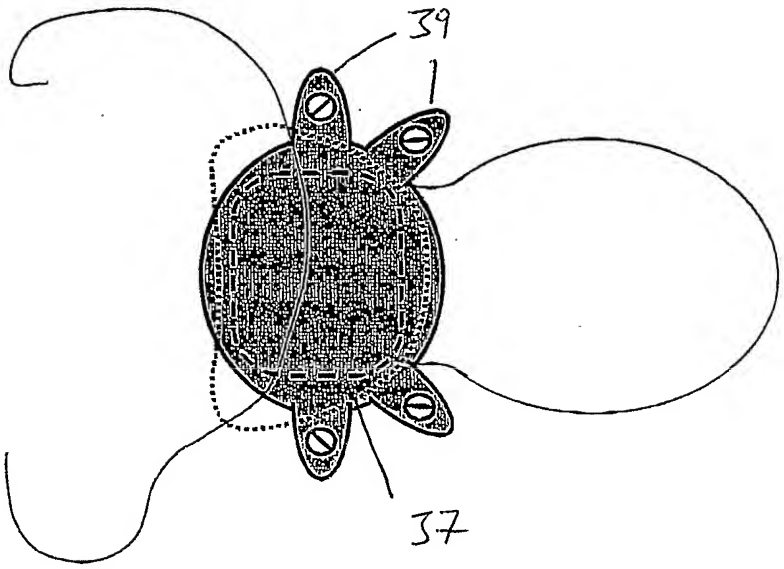

Figure 5

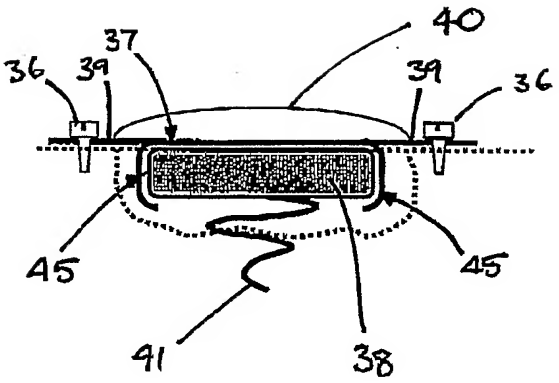

Figure 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU03/01012

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61F 11/00, A61B 17/56

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
Refer electronic databases consulted below

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI +keywords: implant, bone, cavity, flange, housing and similar terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,427,086 B1 (FISCHELL et al) 30 July 2002 column 34 line 62 to column 35 line 56, figures 27 and 28	1-36, 41, 42
X	US 6,132,384 A (CHRISTOPHERSON et al) 17 October 2000 column 10 lines 48 to 57, figures 10b and 11b	1-6, 11-16
A	US 4,904,233 A (HÅKANSSON et al) 27 February 1990 abstract	

[X] Further documents are listed in the continuation of Box C [X] See patent family annex

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 September 2003	13 OCT 2003
Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**SUE THOMAS** Telephone No : (02) 6283 2454

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU03/01012

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 01/10369 A1 (THE UNIVERSITY OF MELBOURNE) 15 February 2001 Abstract	
A	US 5,814,095 A (MÜLLER et al) 29 September 1998 Abstract, figure 2	
A	US 5,906,635 A (MANIGLIA) 25 May 1999 Abstract	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU03/01012

Supplemental Box
(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: II

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-21 are directed to a medical implant for implantation in a cavity of a bone including an upper surface with a flange member extending outwardly and adapted to abut the surface of the bone surrounding the cavity. It is considered that a a flange to abut the surface of the bone comprises a first "special technical feature".

2. Claims 22-36, 41 and 42 are directed to an implantable component and its method of implantation of a tissue stimulating prosthesis including a protective faceplate. It is considered that the faceplate of a tissue stimulating prosthesis comprises a second "special technical feature".

3. Claims 37-40 are directed to a method of implanting a medical implant having a lower conformable surface including the steps of forming or selecting a cavity in the bone and conforming the lower surface of the implant to match the shape of the cavity of the bone. It is considered that an medical implant with lower conformable surface comprises a third "special technical feature".

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, *a priori*.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU03/01012

Box I **Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos :

because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos :

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos :

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II **Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

Claims 1-21
Claims 22-36, 41 and 42
Claims 37-40

See supplemental box

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.: 1-42

It was decided that the fees paid were sufficient to cover all claims.

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☒ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU03/01012

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	6427086	EP	0911061	EP	1145735	EP	1145736
		US	6016449	US	6061593	US	6128538
		US	6134474	US	6230049	US	6354299
		US	6360122	US	6466822	US	6480743
		US	6597954	US	2001051819	US	2001056290
		US	2002002390	US	2002072770	US	2002077670
		US	2002099412	US	2002169485		
US	6132384	AU	35800/97	CA	2258289	EP	0917485
		US	6572543	WO	9749454		
US	4904233	SE	8502341				
WO	0110369	AU	62542/00	CA	2378392	EP	1202693
US	5814095	DE	19638158	DE	19638159	EP	0831673
		EP	0831674				
US	5906635	US	5558618	US	6161046		

END OF ANNEX